

Food and Drug Administration, HHS

§ 73.1299

Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 721(c) of the act.

§ 73.1298 Ferric ammonium ferrocyanide.

(a) *Identity.* (1) The color additive ferric ammonium ferrocyanide is the blue pigment obtained by oxidizing under acidic conditions with sodium dichromate the acid digested precipitate resulting from mixing solutions of ferrous sulfate and sodium ferrocyanide in the presence of ammonium sulfate. The oxidized product is filtered, washed, and dried. The pigment consists principally of ferric ammonium ferrocyanide with smaller amounts of ferric ferrocyanide and ferric sodium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ammonium ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Ferric ammonium ferrocyanide shall conform to the following specifications and shall be free of impurities other than those named to the extent that the other impurities may be avoided by good manufacturing practice:

Oxalic acid or its salts, not more than 0.1 percent.

Water soluble matter, not more than 3 percent.

Water soluble cyanide, not more than 10 parts per million.

Volatile matter, not more than 4 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Nickel (as Ni), not more than 200 parts per million.

Cobalt (as Co), not more than 200 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total iron (as Fe corrected for volatile matter), not less than 33 percent and not more than 39 percent.

(c) *Uses and restrictions.* Ferric ammonium ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 44 FR 28322, May 15, 1979]

§ 73.1299 Ferric ferrocyanide.

(a) *Identity.* (1) The color additive ferric ferrocyanide is a ferric hexacyanoferrate pigment characterized by the structural formula $\text{Fe}_4[\text{Fe}(\text{CN})_6]_3 \cdot \text{XH}_2\text{O}$, which may contain small amounts of ferric sodium ferrocyanide and ferric potassium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Ferric ferrocyanide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice: